

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 1 and 20

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[Docket Nos. 2002N-0276 and 2002N-0278]

**Interim Final Regulations Implementing Title III, Subtitle A, of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002—
Section 305: Registration of Food Facilities and Section 307: Prior Notice of Imported Food Shipments; Notice of Public Meeting**

AGENCY: Food and Drug Administration, HHS.

ACTION: Public meetings on interim final rules.

SUMMARY: The Food and Drug Administration (FDA) is announcing a series of domestic meetings to discuss the interim final regulations, issued on October 10, 2003, to implement two sections of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (Bioterrorism Act) regarding the registration of food facilities and prior notice of imported food shipments. The purpose of these meetings is to provide information on the rules to the public and to provide the public an opportunity to ask questions of clarification.

DATES: See table 1 of the **SUPPLEMENTARY INFORMATION** section of this document.

ADDRESSES: See table 1 of the **SUPPLEMENTARY INFORMATION** section of this document.

FOR FURTHER INFORMATION CONTACT: Marion V. Allen, Center for Food Safety and Applied Nutrition (HFS-32), Food and Drug Administration, 5100 Paint

Branch Pkwy., College Park, MD 20740, 301-436-2277, FAX: 301-436-2605, e-mail: *CFSAN-FSS@cfsan.fda.gov* for general questions about the meeting.

SUPPLEMENTARY INFORMATION:

I. Background

The events of September 11, 2001, highlighted the need to enhance the security of the U.S. food supply. Congress responded by passing the Bioterrorism Act (Public Law 107-188), which was signed into law on June 12, 2002. On October 10, 2003, FDA published in the **Federal Register** two interim final rules to implement sections 305 (Registration of Food Facilities) and 307 (Prior Notice of Imported Food Shipments) of the Bioterrorism Act. During the public meetings, FDA will explain the interim final rules on the registration of food facilities and prior notice of imported food shipments, and the agency will answer questions of clarification.

Information about the public meetings, contact information, and the provisions of the Bioterrorism Act under FDA's jurisdiction can be accessed at <http://www.fda.gov/oc/bioterrorism/bioact.html>.

II. Interim Final Rules

The interim final rules that will be discussed at the public meetings announced in this document concern the following provisions of the Bioterrorism Act:

Section 305: Registration of Food Facilities—The Bioterrorism Act requires the owner, operator, or agent in charge of domestic and foreign facilities that manufacture, process, pack, or hold food for human or animal consumption in the United States to register with FDA no later than December 12, 2003. Farms, restaurants, retail food establishments, nonprofit food establishments that prepare or serve food directly to the consumer, and fishing vessels not

engaged in processing, as defined in 21 CFR 123.3(k), are exempt from this requirement. Also exempt are foreign facilities if the food from the facility undergoes further processing or packaging by another facility outside of the United States and such processing is of more than a de minimis nature.

Section 307: Prior Notice of Imported Food Shipments—The Bioterrorism Act specifies that beginning on December 12, 2003, FDA must receive prior notice of each article of food imported or offered for import into the United States.

III. Registration for the Meetings

All attendees are asked to register for these meetings by submitting registration information (including name, title, firm name, address, telephone number, e-mail address, and fax number) at least 2 workdays before the particular meeting date. You may register online at <http://www.cfsan.fda.gov/dms/fsbtac15.html> or by fax at 202–479–6801. Space is limited, and registration will be closed at a site when maximum seating capacity for that site is reached (between 100 and 200 persons per site).

If you need special accommodations due to a disability, please notify the contact person listed in the **FOR FURTHER INFORMATION CONTACT** section of this document.

IV. Dates, Times, and Addresses of Public Meetings

A list of dates, times, and addresses for the domestic meeting is provided in table 1:

TABLE 1.—NOVEMBER 2003, DOMESTIC OUTREACH MEETINGS—SECTION 305: REGISTRATION OF FOOD FACILITIES AND SECTION 307: PRIOR NOTICE OF IMPORTED FOOD SHIPMENTS

| Meeting Address | Date and Local Time | FDA Contact Person |
|---|---|--------------------|
| DETROIT: Marriott Detroit Metro Airport, 30559 Flynn Rd., Romulus, MI 48174 | Wednesday, November 12, 2003, 9 a.m. to 12 noon | Marion Allen |
| LOS ANGELES: Hilton-Los Angeles Airport, 5711 West Century Blvd., Los Angeles, CA | Friday, November 14, 2003, 9 a.m. to 12 noon | Do. |

TABLE 1.—NOVEMBER 2003, DOMESTIC OUTREACH MEETINGS—SECTION 305: REGISTRATION OF FOOD FACILITIES AND SECTION 307: PRIOR NOTICE OF IMPORTED FOOD SHIPMENTS—Continued

| Meeting Address | Date and Local Time | FDA Contact Person |
|---|--|--------------------|
| JAMAICA QUEENS: La Guardia Airport Marriott Hotel, Ditmars Blvd., East Elmhurst, NY 11369 | Monday, November 17, 2003, 9 a.m. to 12 noon | Do. |
| SAN ANTONIO: Westin Riverwalk, 420 West Market St., San Antonio, TX 78205 | Tuesday, November 18, 2003, 9 a.m. to 12 noon | Do. |
| MIAMI: Marriott Miami Airport, 1201 NW LeJeune Rd. Miami, FL | Thursday, November 20, 2003, 9 a.m. to 12 noon | Do. |
| BALTIMORE: Hyatt Regency, 300 Light St., Baltimore, MD | Friday, November 21, 2003, 9 a.m. to 12 noon | Do. |

Dated: 10/22/03
October 22, 2003.

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Jeffrey Shuren,
Assistant Commissioner for Policy.

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